UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	)	**Criminal No.: 09-CR-10330-GAO**
v.	)	
(1) STRYKER BIOTECH, LLC,	)	
(2) MARK PHILIP,	)	
(3) WILLIAM HEPPNER,	)	
(4) DAVID ARD and	)	
(5) JEFFREY WHITAKER,	)	
Defendants.	)	

GOVERNMENT'S OPPOSITION TO DEFENDANT STRYKER BIOTECH LLC's MOTION TO DISMISS COUNT 13

The United States hereby opposes Defendant Stryker Biotech LLC's Motion to Dismiss Count Thirteen, charging a false statement in violation of 18 U.S.C. §1001.

INTRODUCTION

Defendant Stryker Biotech, LLC ("Stryker") moves to dismiss Count 13, charging it with making a false statement to the FDA in its 2007 Annual Report for OP-1 Putty. The motion must be denied for independent legal and factual reasons: (1) as a legal matter, it emphasizes a "collective intent" theory, which is not required under the operative 18 U.S.C. §1001 statute, and ignores controlling First Circuit law on the "collective knowledge" doctrine which is potentially relevant to the charge; and (2) as a factual matter, the motion makes a series of assertions about what the government can or cannot prove as to various individuals at Stryker who were involved with the false statement, including its former president Mark Philip, and ignores the mandate that the factual allegations in a lawfully returned indictment must be taken as true and resolved by the

jury.[1]

As set forth in more detail below, Stryker's motion comes nowhere close to meeting the high standard to dismiss a charge in a lawfully returned indictment. Rather than mention that standard, or the array of facts set forth in the Superseding Indictment that support the charge in Count 13, Stryker argues its version of a sliver of the facts at issue, and couples that with the repetition of a theory of "collective intent" that is not relevant to the false statement charged in Count 13.

BACKGROUND

A. The Operative Charge

The Superseding Indictment, returned on October 11, 2011, charges in Count 13 a valid violation by Stryker of 18 U.S.C. §1001. The crux of the charge is that in April 2007, Stryker falsely told the United States Food & Drug Administration ("FDA") that it had treated fewer than 4,000 patients during the "year" April 1, 2006 through March 31, 2007, and that 2 units of OP-1 "are" used per patient. The Superseding Indictment charges that these statements were materially false and that Stryker knew them to be false.

On April 7, 2004, Stryker obtained from the FDA a Humanitarian Device Exemption ("HDE") for Stryker's medical device, OP-1 Putty, a bone morphogenic protein to be used

[1]Despite Stryker's assertion that it now understands that Count 13 is based on a "collective intent" theory, which it is not, there is nothing new about Count 13. It is the same charge in the original Indictment (there Count 15) which Stryker never moved to dismiss. Even before the Superseding Indictment, Stryker had articulated the same arguments it makes here. See Stryker's Memorandum in Support of Motion to Sever dated September 14, 2001 (Docket Entry #136 at p. 8)(noting that the charge would turn on "the narrow issues of intent and materiality, the former of which will likely turn on the predicate legal question of whether the concepts of 'collective intent' and 'collective knowledge' apply to a Section 1001 prosecution.").

during invasive spinal surgeries. Superseding Indictment ¶20. The HDE did not require a showing of efficacy, rather Stryker only had to show the FDA that the device did not pose an unreasonable or significant risk of injury, and that the probable benefit to health outweighed the risk of injury from its use, taking into account the probable risks and benefits of currently available devices. Superseding Indictment ¶5D. To obtain the HDE for OP-1 Putty, Stryker had to show, among other things, that there were no comparable devices to treat the condition. Id.

The HDE came with a number of significant requirements and restrictions. For example, an HDE could only be granted upon a finding by the FDA that the device was designed to treat or diagnose a condition that affected fewer than 4,000 individuals in the United States. Superseding Indictment ¶5D(1). Stryker represented to the FDA that OP-1 Putty was designed to treat a condition that affected fewer than 4,000 individuals in the United States, namely individuals who required revisionary posterolateral lumbar fusion for whom autologous bone and bone marrow harvest were not feasible. Superseding Indictment ¶20.

Stryker was required to submit annual reports to the FDA for OP-1 Putty and to include in those annual reports information on the number of devices that had been shipped or sold, and if the number exceeded 4,000 to provide an explanation and estimate of the number of devices used per patient and in turn the number of patients treated. Superseding Indictment ¶45. Based on the clinical trial data submitted by Stryker to the FDA, the FDA approved label for OP-1 stated "one unit of OP-1 Putty . . . will be used on each side of the spine." Superseding Indictment ¶46. Each unit of OP-1 Putty cost over $5,000 and therefore the cost as labeled per surgery for the OP-1 would exceed $10,000. Id., ¶47. Accordingly, 2 units of OP-1 Putty were rarely used in spinal surgeries; most sales of OP-1 Putty were of one unit per patient per surgery.

Id.

In 2005, Stryker prepared various analyses of the average number of OP-1 Putty units used per patient. Id., ¶48. These analyses concluded that Stryker was not selling two units per patient, but rather approximately 1.3 units per patient. Id. This difference made a significant economic difference to Stryker. At a 4,000 patient limit, if 2 units were sold per patient, Stryker could sell 8,000 units, and at price of $5,000 per unit, generate $40 million in annual sales. However, if only 1.3 units were used per patient (4,000 patients x 1.3 units per patient = 5,200), only 5,200 units of OP-1 Putty could be sold, and at a price of $5,000 per unit, Stryker could only generate $26 million in annual sales. Superseding Indictment ¶¶49-50. This difference of $14 million per year was significant to Stryker's finances.

In 2005, Stryker knew that there were "[s]ignificant risks associated with exceeding patient limit," including potentially losing its HDE for OP-1 Putty. Superseding Indictment ¶49. Despite the knowledge of the actual usage of OP-1 Putty and the risks of exceeding the 4,000 patient limit, in 2006 and 2007 Stryker adopted budgets and quotas that called for the sale of more than 5,200 units of OP-1 Putty. Superseding Indictment ¶50.

By letter dated April 30, 2007, Stryker made a false statement to the FDA in its 2007 Annual Report for OP-1 Putty:

> Since the last reporting period, 6,234 units of OP-1 Putty have been sold to IRB-approved institutions throughout the United States. Since 2 units of OP-1 Putty are used per patient, it is estimated that 3,117 patients have been treated during this reporting period.

Superseding Indictment ¶51. This statement was false in that Stryker knew that 2 units of OP-1 Putty were not used per patient (rather it was approximately 1.3) and therefore more than 4,000 patients had been treated (6,234/1.3 = 4,795). Superseding Indictment ¶68.

In October 2007, in connection with an FDA inspection, a Stryker employee advised Stryker's then president, Mark Philip that the actual usage data for OP-1 Putty did not support the usage of 2 units of OP-1 Putty per patient and provided Philip with an analysis that showed the average usage was approximately 1.3 units of OP-1 Putty per patient. Superseding Indictment ¶52. This was the same type of analysis (and reached the same conclusion) that had been prepared by Stryker in 2005. Id., ¶48. Philip's reaction to being presented with this analysis was to ask the two Stryker employees who brought it to him in October 2007 to delete the written analysis. Id., ¶53. A few months later, in February 2008, in advance of a conference call with management of Stryker's parent company, Philip asked a Stryker colleague to say something on the call that was not true, namely that Stryker had no way to track the per patient usage of OP-1 Putty. Id., ¶54.

As Stryker points out in its Memorandum at p. 2, footnote 3, the false statement made by Stryker to the FDA on April 30, 2007 remained uncorrected until April 2008 when Stryker "voluntarily informed the FDA that, based on a reassessment of historical sales invoices, it was likely that more than 4,000 patients had been treated with OP-1 Putty during both the 2007 and 2008 reporting periods." Of course by this time, Philip no longer was employed at Stryker, see Superseding Indictment ¶13, and therefore no longer was part of the annual reporting process.

ARGUMENT

A. The Legal Standard For Motions to Dismiss.

"In the normal course of events, a facially valid indictment returned by a duly constituted grand jury calls for a trial on the merits." United States v. Stokes, 124 F.3d 39, 44 (1st Cir. 1997). "Because the public maintains an abiding interest in the administration of criminal

justice, dismissing an indictment is an extraordinary step." United States v. Li, 206 F.3d 56, 62 (1st Cir. 2000) (internal citations and quotations omitted). In a motion to dismiss, the court must assume that the government's factual allegations are true. E.g. United States v. Bohai Trading Co., Inc., 45 F.3d 577, 578 n.1 (1st Cir. 1995). See also United States v. Maceo, 873 F.2d 1, 3 (1st Cir. 1989)("A court should not inquire into the sufficiency of the evidence before the indicting grand jury"). An indictment need only be a "plain, concise, and definite written statement of the essential facts constituting the offense charged. . ." Fed. R. Crim. P. 7(c). An indictment "is sufficient when allegations are made in the language of the statute as long as the core facts of the criminality charged are also included." United States v. Barker Steel Co., Inc., 985 F.2d 1123, 1126 (1st Cir. 1993). Moreover, "[i]ndictments 'must be read to include facts which are necessarily implied by the specific allegations made.'" United States v. Cincotta, 689 F.2d 238, 242 (1st Cir. 1982) (quoting United States v. Barbato, 471 F.2d 918, 921 (1st Cir. 1973) (citations omitted)). Stryker's motion does not challenge the sufficiency of the Superseding Indictment; it merely quarrels with the manner in which it believes the government will prove the *mens rea* element of the crime.

In its motion papers, Stryker bothers neither with the actual allegations in the Superseding Indictment nor any argument as to how it meets the high standard for obtaining dismissal of the Superseding Indictment. The combination of the legal standard and the factual allegations, which must, at this stage, be assumed as true, demonstrates that the motion must be denied.

B. Stryker's False Statement Does Not Rest on a Collective Intent Theory.

In its motion, Stryker skips over the actual charges and the legal standard for a motion to dismiss and begins by arguing that a false statement may not rest on a theory of "collective intent." Then, by dint of mere repetition, Stryker tries to heighten the well-established intent requirement of a false statement into one involving a specific intent to deceive, and then argues that "collective intent" cannot be used against Stryker. This legal legerdemain fails in the face of the facts set forth in the Superseding Indictment, and the law in the First Circuit on false statements.

As noted, Stryker's arguments ignore the Superseding Indictment and the elements of the false statement offense. Title 18 U.S.C. §1001 provides that it is a crime to "knowingly and willfully" make a "materially false" statement in a matter within the jurisdiction of a branch of the Government of the United States. Stryker focuses its argument on the statute's "willfully" language, but incorrectly argues that the government seeks to use a "collective intent" theory to demonstrate that Stryker acted "willfully." The primary problem with Stryker's argument is its failure to focus on the actual elements of the false statement crime.

The "willfully" element of §1001 does not require any "intent to deceive." United States v. Gonsalves, 435 F.3d 64, 72 (1st Cir. 2006). The First Circuit in Gonsalves held that willfullness:

> means nothing more in this context than that the defendant knew that his statement was false when he made it or–which amounts in law to the same thing–consciously disregarded or averted his eyes from its likely falsity.

Id. This is exactly the manner in which the government is proceeding on Count 13. Stryker, as a corporation knew its statement to the FDA was false, or having information at various levels of

the company about the real usage of OP-1 Putty, it consciously disregarded or averted its eyes from the likely falsity of its 2007 Annual Report for OP-1 Putty.

Stryker misapprehends the meaning of "willfully" in the false statement statute, and seeks to import an intent to deceive to that word when it is well settled that it has no such meaning. In fact, the Pattern Jury Instructions for the First Circuit for 18 U.S.C. §1001 do not even use the word "willfully," instead stating that a "false statement is made 'knowingly' if defendant knew that it was false or demonstrated a reckless disregard for the truth with a conscious purpose to avoid learning the truth."[2] First Circuit Criminal Pattern Jury Instructions, 4.18 (1998). Accord, United States v. Riccio, 529 F.3d 40, 44, 47 (1st Cir. 2008)(affirming conviction when jury instructions on false statement charge did not use word "willfully" but correctly described elements of offense).

In an effort to heighten the intent element of a false statement and argue that under that heightened intent the government cannot proceed under a collective intent theory, Stryker relies on a series of inapposite cases ranging from False Claims Act cases under an implied certification theory (United States v. Science Applications International Corp., 626 F.3d 1257 (D.C. Cir. 2010)) to a civil RICO case (Chaney v. Dreyfus Service Corp., 595 F.3d 219 (5th Cir. 2010)) to a state involuntary manslaughter case (Commonwealth v. Life Care Ctrs. of America, Inc., 456 Mass. 826 (2010)). However, the Court should reject the invitation to engraft a

[2]Judge Hornby's update to the Pattern Jury Instructions for the First Circuit do use the word "willfully" but define it exactly as the term "knowingly" in the First Circuit Pattern Jury Instructions: "A false statement is made 'knowingly and willfully' if the defendant knew that it was false or demonstrated a reckless disregard for the truth with a conscious purpose to avoid learning the truth." Judge D. Brock Hornby's Revisions to Patter Criminal Jury Instructions for the District Courts of the First Circuit, 4.18.1001 (updated June 17, 2008).

heightened intent element onto the false statement statute. United States v. Yermian, 468 U.S. 63, 73 (1984); United States v. Riccio, 529 F.3d at 47 ("In Gonsalves, we expressly rejected the argument that § 1001 requires 'an intent to deceive.'"). Moreover, the government has no need to and is not proceeding under a collective intent theory.

Its inapposite arguments against collective intent appear to be part of Stryker's efforts to escape established First Circuit law on collective knowledge, a different and potentially applicable concept here. In United States v. Bank of New England, N.A., 821 F.2d 844 (1st Cir. 1987), the First Circuit affirmed convictions under the Currency Transaction Reporting Act, which imposes felony liability when a bank "willfully" fails to file certain reports. On appeal, the bank argued that the trial court's instructions on "knowledge and specific intent effectively relieved the government of its responsibility to prove that the Bank acted willfully." Id. at 854. In the context of the Currency Transaction Reporting crimes at issue, the First Circuit noted that willfulness "must be supported by proof of the defendant's knowledge of the reporting requirements and his specific intent to commit the crime." Id. (omitting internal quotations and citations). In the context of the false statement charge against Stryker, as demonstrated above, willfulness under §1001 has a knowledge-based meaning: the defendant knew the statement was false when made or consciously disregarded or averted his eyes from its likely falsity. This is important because the "collective knowledge" concept endorsed by the First Circuit in Bank of New England obviously applies to proving knowledge.

On that front, the First Circuit held that as an institution the bank's "knowledge is the sum of the knowledge of all of the employees. That is, the bank's knowledge is the totality of what all of the employees know within the scope of their employment." Id. at 855. The First

Circuit went on to hold:

> A collective knowledge instruction is entirely appropriate in the context of corporate criminal liability. The acts of a corporation are, after all, simply the acts of all of its employees operating within the scope of their employment. The law on corporate criminal liability reflects this. Similarly, the knowledge obtained by corporate employees acting within the scope of their employment is imputed to the corporation. Corporations compartmentalize knowledge, subdividing the elements of specific duties and operations into smaller components. The aggregate of those components constitutes the corporation's knowledge of a particular operation. It is irrelevant whether employees administering one component of an operation know the specific activities of employees administering another aspect of the operation [.] A corporation cannot plead innocence by asserting that the information obtained by several employees was not acquired by any one individual who then would have comprehended its full import. Rather the corporation is considered to have acquired the collective knowledge of its employees and is held responsible for their failure to act accordingly. Since the Bank had the compartmentalized structure common to all large corporations, the court's collective knowledge instruction was not only proper but necessary.

Id. at 856.

Thus the First Circuit has already specifically rebutted the arguments Stryker is now making. The government need not show that Mark Philip or any other person at Stryker knew everything that other Stryker employees knew. At trial, there will be evidence about what a variety of Stryker employees, from sales representatives to marketing managers to sales managers to senior executives, including Mark Philip, knew about the average number of units of OP-1 Putty sold per surgery. As the First Circuit found in Bank of New England, given the corporate structure, it is "necessary" to deem Stryker to be in possession of all the knowledge of its employees. Id. While there may be limitations on aggregating specific intent, the First Circuit's holding in Bank of New England does not limit aggregation of corporate knowledge.

As made clear in Bank of New England, the government has at least three options for proving the "knowingly and willfully" element of §1001: (1) demonstrate that one of the Stryker

employees knew that the statements in the annual report were false; (2) demonstrate that one of the Stryker employees consciously disregarded or averted his eyes from its likely falsity; (3) aggregate the knowledge of all Stryker employees to demonstrate the falsity or the conscious disregard. The government expects to adduce evidence at trial in support of all three options.

With respect to the proof related to an individual employee, Stryker argues that the charges do not support that its former president Mark Philip "made a false statement to the FDA." Stryker Memo at 8. Putting aside, Stryker's scant and slanted selection of the "evidence," the fact that Stryker is discussing any evidence demonstrates the impropriety of a motion to dismiss. The jury must decide based on the evidence at trial.

As a matter of law and fact, there is no basis for a dismissal of Count 13.

CONCLUSION

For the foregoing reasons, the United States respectfully requests that the Court deny Stryker's Motion to Dismiss Count Thirteen.

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Dated: November 23, 2010

Certificate of Service

I hereby certify that the foregoing documents filed through the ECF system will be sent electronically to counsel for each defendant who is a registered participant as identified on the Notice of Electronic Filing (NEF).

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Dated: November 23, 2010